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satisfaction" as full strength cigarettes.[911] Philip Morris' arguments with respect to the methods used to control nicotine-to-tar ratios are addressed in sections II.C.4., above, and section II.C.6.c.ii., below.

Tobacco industry comments also state that Farone fails to acknowledge that, beginning in the 1970's, outside scientists recommended that research be conducted on the development of a high nicotine/low tar cigarette. This argument has already been addressed above in section II.C.3.f. In this context, FDA notes that Farone is reporting on the tobacco industry's *internal* reasons for conducting the research, and these reasons are relevant to establishing the companies' intent to affect the structure or function of the body.

4. Philip Morris challenges the reliability of statements made in a declaration submitted to FDA by Ian L. Uydess, a research scientist who worked for Philip Morris from 1977 to 1981, and from 1982 to 1989. Uydess' declaration is based on his own participation in research and development projects at Philip Morris; his personal observations of activities in other parts of the company; his attendance at meetings and discussions held among the scientists, engineers and management at Philip Morris; and his close association with other scientists and senior management at Philip Morris.[912] Philip Morris argues that the information provided by Uydess is unreliable because: (1) he left Philip Morris seven years ago; (2) he did not work on the development of commercial cigarettes; and (3) his declaration reports, in part, on information relayed to him informally

[911] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 7. *See* AR (Vol. 638 Ref. 2).

[912] Declaration of Uydess IL (Feb. 29, 1996), at 5. *See* AR (Vol. 638 Ref. 1).

by colleagues. In contrast, other comments argue that the reliability of Uydess' statement is shown by its consistency with the statement of other former tobacco company officials.

FDA disagrees that Uydess' declaration is unreliable or irrelevant to establishing the knowledge and actions of Philip Morris. His position and tenure at the company gave him personal knowledge of the views of Philip Morris officials on the role of nicotine in cigarettes, and of the company's research and actions in developing new products. Moreover, like Farone, Uydess' statements about the knowledge, views, and actions of Philip Morris are consistent with a large body of Philip Morris documents and statements, covering over three decades. Uydess' statements are also consistent with the recent Philip Morris document concerning Project Table, demonstrating that the company's views have not changed since Uydess left the company. The information he provided is thus corroborated by evidence already gathered by FDA.

5. Philip Morris also challenges particular statements made by Uydess in his declaration. FDA addresses those comments that challenge statements relied on by the Agency.

Philip Morris argues that Uydess' statement that Philip Morris conducted exhaustive research on nicotine chemistry in tobacco leaf and tobacco smoke is true but irrelevant because: (1) any manufacturer in the business of selling an agricultural product develops expertise in the product; (2) tobacco chemistry is widely studied outside Philip Morris; and (3) the company's research was not used to increase artificially the nicotine yield of its commercial cigarettes.

FDA disagrees that extensive research by a tobacco manufacturer into the amount of nicotine in tobacco leaf and tobacco smoke—using highly sophisticated equipment

developed, in part, by the company—is irrelevant to the manufacturer's intent in selling cigarettes. Philip Morris' arguments suggest that Uydess' statement relates to the company's research on tobacco chemistry in general, rather than to any specific component in tobacco. Uydess says, however, that Philip Morris' exhaustive research related specifically to nicotine and that Philip Morris "wanted to know everything there was to know about nicotine."[913] The intensity of Philip Morris' focus on nicotine provides evidence that the company knows that nicotine is central to the success of its products.

Philip Morris' public position is that if nicotine is important, it is important, like flavorants, only for its sensory appeal. The company, however, offers no evidence or argument that its exhaustive research on nicotine pharmacology is matched by its research on any other flavor or sensory aspects of nicotine. Moreover, as described in section II.C.2.a., above, Philip Morris' public position is contradicted by the views of its scientists, who have repeatedly stated that the primary reason for smoking is nicotine's pharmacological effects. FDA concludes that the extent of Philip Morris' research on nicotine is relevant to establishing its intent to affect the structure or function of the body.

ii. Comments on Specific RJR Product Research and Development Projects.

1. RJR contends that Premier and Eclipse are not "alternative cigarettes" but conventional cigarettes, and that they were created to address public criticisms of cigarettes. RJR also disputes FDA's findings that Premier contained very little tobacco and that the nicotine in blood studies conducted on Premier show that RJR intended Premier to deliver nicotine to the smoker's blood and brain.

[913] *Id.* at 14.

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RJR's arguments concerning Premier and Eclipse are not persuasive. RJR now claims that Premier was a conventional cigarettes because it was a "roll of tobacco wrapped in paper"; "contained sugars, humectants, flavorings, tobacco paper, and a filter"; was "taxed as a cigarette"; and was "marketed for smoking taste and pleasure."[914] In fact, Premier resembled a conventional cigarette in outward appearance only. It contained a carbon tip that served as the heat source. A nicotine source had been combined with glycerol and adsorbed within alpha-alumina spheres contained within an aluminum cylinder positioned directly behind the carbon heat source. RJR informed FDA that at least 70% of the nicotine delivered by Premier was provided from spray-dried tobacco. The remaining nicotine was provided from the cut tobacco leaf surrounding this cylinder and the tobacco extract-treated paper filter positioned in front of the cellulose acetate filter.[915] Although there was a small amount of tobacco in Premier, it was not burned; the only component of Premier that was burned was the carbon heat source and some paper, to "simulate[] the ash of other cigarettes."[916]

The critical aspect of Premier is the fact that the major constituents of its smoke differed from those in the smoke of conventional cigarettes in almost every way except nicotine content.[917] In other words, virtually the only constituent of tobacco smoke that RJR designed Premier to preserve was nicotine.

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[914] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), 35. *See* AR (Vol. 519 Ref. 103).

[915] Letter with enclosures from Hutt PB, outside counsel for RJR, to Budich KM, FDA (Jan. 26, 1988). *See* AR (Vol. 34 Ref. 556).

[916] R.J. Reynolds Tobacco Co., *Chemical and Biological Studies on New Cigarette Prototypes That Heat Instead of Burn Tobacco* (Winston-Salem NC, 1988), at 4. *See* AR (Vol. 107 Ref. 980).

[917] *Id.* at 134-136.

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FDA does not contest that Premier was developed to address criticisms of cigarettes; undoubtedly, Premier was an attempt to make a safer cigarette. However, making a safer cigarette would not require the company to maintain a near-normal nicotine delivery, or to ensure that the nicotine was actually delivered to the smoker's blood in the same quantity as from conventional cigarettes, unless the company believed that ensuring near-normal nicotine blood levels was an essential feature of a profitable cigarette. RJR's argument that its pharmacokinetic comparisons of the nicotine levels delivered by Premier and a conventional cigarette were intended simply as comparisons of the two products, apparently without any further purpose, is unpersuasive. According to RJR's publication summarizing the studies conducted on Premier, RJR did not conduct similar pharmacokinetic studies on the delivery of any other smoke constituent to the smoker's blood.[918] This fact demonstrates that RJR believes that nicotine is the defining ingredient of cigarettes and that delivery of an adequate level of nicotine to the smoker's blood is central to the success of its products.

The RJR nicotine blood level study is also directly at odds with the company's public position that nicotine's role is limited to providing taste or flavor. The amount of nicotine delivered into a smoker's bloodstream is irrelevant to nicotine's ability to function as a flavoring agent. Nicotine absorption into the bloodstream is relevant only if the company believes that nicotine delivers pharmacological effects to the smoker and that these effects are important to the use of the product. RJR's reliance on a Surgeon General recommendation that cigarettes with low tar-to-nicotine ratios be evaluated for their

[918] *Id.* at 457-557.

pharmacological properties and effects on compensation[919] merely underscores RJR's understanding that the nicotine in cigarettes delivers pharmacological effects and that consumers use cigarettes for these effects.

RJR's last argument, that its study was necessary because an FDA representative later asked whether nicotine was delivered by Premier in amounts comparable to conventional cigarettes, is similarly unavailing. As RJR acknowledges in its comment, the study had already been conducted at the time FDA asked the question. Moreover, FDA asked this question because FDA saw the delivery of nicotine to the blood of smokers as relevant to whether Premier should be regulated as a drug or device.

2. RJR also argues that FDA has misused an RJR book on tobacco flavors in the Jurisdictional Analysis. FDA noted that the book, which contains over one thousand flavorants for tobacco, does not list nicotine as a flavorant.[920] RJR contends that the book describes only flavors that could be added to tobacco, and nicotine is not listed because RJR does not add nicotine.

FDA does not find RJR's argument persuasive. Even if the book were limited to flavors that "could be added" to tobacco (a limitation that is not stated in the book itself), the claim that RJR does not use it as an additive would not logically exclude it from the category of substances that "could" be added. The book does not purport to list only those substances that are actually added by RJR to its tobacco products.

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[919] Department of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette, A Report of the Surgeon General, 1981*, at 58. *See* AR (Vol. 123 Ref. 1586).

[920] Leffingwell JC, Yound HJ (R.J. Reynolds Tobacco Co.), *Tobacco Flavoring for Smoking Products* (Winston-Salem NC: R.J. Reynolds Tobacco Co., 1972). *See* AR (Vol. 34 Ref. 591).

Moreover, RJR's claim that it does not add nicotine raises an inconsistency. If it is the company's position that nicotine is benignly used (and controlled) in tobacco solely for its effects on flavor, and is an extremely important flavorant in tobacco, why have a policy—as RJR claims[921]—of not adding it when appropriate? The book does list many other naturally occurring components of tobacco and tobacco smoke as flavorants, apparently contemplating their addition to tobacco. That RJR policy in itself therefore seems at odds with the claim that nicotine is used for flavor.

3. RJR also maintains that FDA's reliance on an RJR patent was misplaced. In the Jurisdictional Analysis, FDA cited an RJR patent for a process that increases the nicotine content of a cigarette but masks the resulting harsh taste of the cigarette.[922] FDA used the patent to show that the tobacco industry wanted to increase nicotine in some cigarettes *despite* its harsh flavor. RJR dismisses the significance of this patent, arguing that FDA has ignored "basic principles of flavor" and that people like harsh flavors. RJR also argues that the patent is irrelevant because the process it described for increasing nicotine and masking the resulting flavor was not used in commercial cigarettes.

RJR's argument is contradicted by its own patent and by the statements of a flavor specialist employed by the company. Both acknowledge that nicotine's harsh flavor can be unpleasant to the smoker and must be masked by the addition of sugars or other chemicals. The patent itself demonstrates that the company, as the assignee of the patent, knows that increasing nicotine past a certain point in low-tar cigarettes produces a harshness that leads to

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[921] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 50. *See* AR (Vol. 519 Ref. 103).

[922] U.S. Patent No. 4,830,028. Lawson JW, Bullings BR, Perfetti TA, R.J. Reynolds Tobacco Company, *Salts Provided from Nicotine and Organic Acid as Cigarette Additives* (May 16, 1989), at C1. *See* AR (Vol. 34 Ref. 593).

rejection by consumers. Rather than simply keep nicotine below that point, as a company would do if nicotine were present solely for flavor, the patent describes a process for increasing nicotine and simultaneously masking its harshness. The claim that the processes in the patent were not used does not in any way undercut FDA's conclusion that the patent demonstrates RJR's knowledge that nicotine's effects on taste are sometimes negatively related to product acceptance, and RJR's desire to increase nicotine content even beyond the point where nicotine has a demonstrably negative effect on taste.

Moreover, an RJR flavor specialist has written that although nicotine is necessary for "satisfaction," its flavor in some tobacco blends is "a 'harshness' which can be choking and unpleasant," requiring that steps be taken to mask nicotine's flavor.[923]

Thus, it is clear that RJR officials recognize that nicotine's flavor is sometimes a liability that must be masked to permit nicotine to fulfill its pharmacological functions.

4. RJR comments that a document that refers to "physiological satisfaction," which FDA cited as an RJR Marketing Report, is in fact an Imperial Tobacco Co. document.[924]

FDA agrees that this document is an Imperial Tobacco Co. document rather than an RJR document. The document is one of dozens of tobacco industry documents in which the term "satisfaction" is used to describe a pharmacological effect. It is therefore relevant to establishing the industry's understanding and use of that term.

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[923] Leffingwell JC (R.J. Reynolds Tobacco Co.), Nitrogen components of leaf and their relationship to smoking quality and aroma, presented at the 30th Tobacco Chemists' Research Conference, at 9. *See* AR (Vol. 28 Ref. 450).

[924] Imperial Tobacco Ltd., *Matinee Marketing Strategy* (1971) ("A cigarette that delivers physiological satisfaction, yet is low in tar and nicotine, must surely be a major objective"), quoted in Memorandum to File from Joyal C (Dec. 27, 1992), at 11. *See* AR (Vol. 27 Ref. 384).

iii. Comments on Specific Brown & Williamson Product Research and Development Projects.

1. A comment from Brown & Williamson argues that FDA has distorted its nicotine research by not recognizing that the research was not commercialized. According to the comment, Project ARIEL was never commercialized.

ARIEL was an alternative cigarette, developed by Charles Ellis, and referred to by BATCO researchers as a "device[] for the controlled administration of nicotine." [925] ARIEL eliminated almost every ingredient of conventional cigarettes other than nicotine. Its purpose was to provide "the same benefits, pleasure and satisfaction without the disadvantages" of a conventional cigarette.[926] The relevance of this product to intent is that it demonstrates that BATCO regarded nicotine as the essential ingredient in, and the source of the pleasure and satisfaction from, cigarettes. ARIEL's development demonstrates Brown & Williamson's knowledge of and belief in nicotine's central role in cigarettes, regardless of its ultimate failure to be accepted by consumers, or Brown & Williamson's decision not to market it.

2. As described above, a BATCO study entitled "Project Wheat" was conducted to determine the level of nicotine preferred by smokers and correlate it with the extent to which the smoker relies on cigarettes to meet "inner needs."[927] A smoker's inner need level was defined by the extent to which the smoker used nicotine to relieve stress,

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[925] Minutes of BATCO Research Conference at Hilton Head Island, SC (Sep. 24–30, 1968), at 3. *See* AR (Vol. 31 Ref. 525).

[926] U.S. Patent No. 3,258,015. Ellis CD, Dean C, Schachner H, *et al.*, Battelle Memorial Institute, *Smoking Device* (Jun. 28, 1966). *See* AR (Vol. 34 Ref. 569).

[927] Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits* (Jul. 10, 1975), at 1. *See* AR (Vol. 20 Ref. 204-1).

aid concentration, avoid weight gain, or reduce craving. BATCO hypothesized that "the inner need dimension was probably defining a requirement for nicotine."[928] FDA pointed out that inner need therefore correlated with the extent to which a smoker used cigarettes for pharmacological effects. Project Wheat was intended to allow BATCO to market cigarettes with different nicotine levels designed to satisfy identified groups of consumers. Brown & Williamson argues that FDA had no basis for concluding that a smoker's inner need was defined by the extent to which the smoker used cigarettes for the drug effects of nicotine, that Project Wheat failed to find any significant correlation between inner need levels and preferred nicotine delivery, that the term "inner need" came from an outside researcher, not BATCO, and that FDA falsely suggested that Project Wheat identified an allegedly "addictive" dose of nicotine.

Brown & Williamson's attempts to discredit FDA's characterization of Project Wheat are not persuasive. FDA relied on the study as evidence that Brown & Williamson had conducted research on the dose of nicotine required by consumers with the purpose of designing cigarettes to satisfy their nicotine requirements. Brown & Williamson acknowledges that Project Wheat was designed to determine whether smokers who smoked to satisfy an "Inner Need" had preferred nicotine delivery levels, and that this information was to be used to design cigarettes to meet their needs.[929] These facts alone demonstrate that it was the tobacco company's intention to produce cigarettes with satisfying doses of nicotine. (Nowhere did FDA state that the study was intended to establish "addictive" doses of nicotine.)

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[928] *Id.* at 5.

[929] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 43–44. *See* AR (Vol. 529 Ref. 104).